



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD
ARLINGTON TX 76011-4511

July 14, 2016

Mr. Christopher Fitz, Radiation Safety Officer
RCHP Billings – Missoula LLC
dba Community Medical Center
2827 Fort Missoula Road
Missoula, Montana 59804

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

The Nuclear Regulatory Commission (NRC) has received letter dated May 26, 2016, from Dean French, M.D., Chief Executive Officer, requesting an amendment to NRC license number 25-18361-01 to authorize the use of Iodine-125 and Palladium-103 low dose brachytherapy seeds for localization of non-palpable lesions (procedure). The NRC has reviewed the amendment request and has determined that the licensee submitted incomplete information. Please provide the following information in a signed and dated letter, in hospital letterhead, within 30 days, and make reference to mail control number 591050.

1. Manufacturer's name and model number of all the potential Iodine-125 and Palladium-103 sealed sources that will be used for this procedure.
2. The training and supervised work experience for Michael A. Stuart, M.D. was not included with the amendment request. Provide training and supervised work experience for Dr. Stuart, obtained under the supervision of a 10 CFR 35.490 (manual brachytherapy) authorized user and preceptor, that includes the following:
 - A. Work experience which includes at least 3 cases, wherein the authorized user ordered, received, and unpacked radioactive material safely;
 - B. Work experience that includes performing the related radiation surveys using the appropriate instrumentation;
 - C. Work experience that includes preparing, implanting, and removing sources safely, to include the use of remote handling tools to manipulate seeds and the proper use of shields;
 - D. Work experience that includes routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source;
 - E. Work experience that includes using emergency procedures, such as procedures regarding broken or leaking seeds;
 - F. Work experience that includes reviewing and understanding the administrative controls in place to prevent a medical event;

- G. Work experience in maintaining running inventories of radioactive material on hand;
and
 - H. Signed and dated receptor attestation documenting that the training described above has been completed under the preceptor's supervision.
3. Provide written procedures that describe the licensee's radiation safety program for all departments involved in this procedure, including surgery and pathology laboratory, that includes the following:
- A. Written procedures for routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source;
and
 - B. Written emergency procedures for responding to an abnormal situation to include:
 - (i) Instructions for responding to a source rupture (e.g. cut by a scalpel) during surgical removal to include procedures for retrieval of leaking/cut sources, contamination control, decontamination of the patient and area from a ruptured source and saturation of the patient's thyroid with stable iodine in the case of an Iodine-125 source rupture;
 - (ii) Instructions to pathology personnel for responding to a leaking/cut source and decontamination of personnel and area;
 - (iii) The process for restricting access to and posting of the implantation/explantation/pathology area in the event of an unaccounted for or ruptured source to minimize the risk of inadvertent exposure from seeds;
 - (iv) Patient follow-up should they not return for explantation, including a commitment to make multiple attempts at contacting the patient and to perform a dose assessment; and
 - (v) Names and telephone numbers of the authorized users and the Radiation Safety Officer to be contacted.
4. Commit to the following actions for all departments involved in the procedure, including the surgery and the pathology laboratory:
- A. Emergency response equipment will be available near each surgery suite and pathology laboratory during specimen handling;
 - B. The activity of sealed sources will be verified prior to each patient implant using an instrument calibrated in accordance with nationally recognized standards or the manufacturer's instructions and retain a record that includes: (i) the radioisotope; (ii) the patient's name or identification number; (iii) the measured activity; and (iv) the name of the individual who measured the activity;

- C. Procedures will be conducted under the supervision of the authorized user, who should consult with the surgeon prior to implanting the sources;
 - D. Surveys will be performed and records will be maintained as described in 10 CFR 35.404 requirements;
 - E. All sources will be accounted for and all records maintain as described in 10 CFR 35.406;
 - F. Procedures will be developed, implemented, and maintained for source accountability from implantation to explantation and final disposal;
 - G. Written waste disposal procedures will be developed, implemented, and maintained for licensed material in accordance with 10 CFR 20.1101, that meet the requirements of the applicable section of Subpart K to 10 CFR 20 and 10 CFR 35.92;
 - H. Patients will be instructed in writing before implantation and agree in writing to return for removal of the radioactive seeds;
 - I. Training will be provided at least annually and covering the topics described in 10 CFR 35.410 and records described in 10 CFR 35.410 will be maintained; and
 - J. All personnel involved with the procedure, including the Radiation Safety Officer, will be trained on routine monitoring and emergency procedures.
5. Submit a description of the equipment to be used in the case of an emergency such as loss or rupture of a seed. This equipment should include gloves, reverse action tweezers, shielded containers, a low energy gamma scintillation survey equipment, and caution radioactive materials labels.
6. Provide commitment that the licensee will maintain records for seed localization in accordance with the requirements for temporary implants to include the following:
- A. 10 CFR 35.2024 - Records of authority and responsibilities for radiation protection programs;
 - B. 10 CFR 35.2026 - Records of radiation protection program changes;
 - C. 10 CFR 35.2041 - Records for procedures for administrations requiring a written directive;
 - D. 10 CFR 35.2060 - Records of calibrations of instruments used to measure the activity of unsealed byproduct materials;
 - E. 10 CFR 35.2067 - Records of leak tests and inventory of sealed sources and brachytherapy sources;
 - F. 10 CFR 35.2075 - Records of the release of individuals containing unsealed byproduct materials or implants containing byproduct material;

- G. 10 CFR 35.2310 - Records of safety instruction;
 - H. 10 CFR 35.2404 - Records of surveys after source implant and removal;
 - I. 10 CFR 35.2406 - Records of brachytherapy source accountability; and
 - J. 10 CFR 35.2432 - Records of calibration measurements of brachytherapy sources.
7. Provide commitment that the licensee will report any medical event, except for those that result from patient intervention, in accordance with 10 CFR 35, Subpart M to include:
- A. 10 CFR 35.3045 - Report and notification of a medical event;
 - B. 10 CFR 35.3047 - Report and notification of a dose to an embryo/fetus or a nursing child; and
 - C. 10 CFR 35.3067 - Report of a leaking source.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,

/RA/

Roberto J. Torres, M.S., Senior Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-14921
License: 25-18361-01
Control: 591050